New Jersey Department of Health and Senior Services (NJDHSS)
Guidelines for Surveillance, Evaluation, Treatment and Management of
Adverse Events Related to Vaccinia Vaccine

These Guidelines describe activities related to potential adverse events from vaccinia vaccine and have been adapted from the Centers for Disease Control and Prevention's (CDC) "Annex 4—Vaccine Adverse Events Report" available at http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp.

The Guidelines include the following topics:

I. Reporting requirements
II. Enhanced passive hospital-based surveillance
III. Active regional vaccination clinic-based surveillance
IV. Data management, information, updates and follow-up procedures
V. Evaluation, treatment and management of adverse events
VI. Contact information
VII. Resources

I. Reporting requirements

A. Vaccine adverse events (VAEs) that are serious or unexpected which require expert consultation or IND therapeutics should be immediately reported by phone to NJDHSS and should also be reported to Vaccine Adverse Events Reporting System (VAERS—additional guidance available in Section II.C.) as soon as possible.

B. All other smallpox VAEs judged to be serious must be reported within 48 hours.

C. Other clinically significant VAEs must be reported within 7 days.

II. Enhanced passive hospital-based surveillance

A. Introduction

1. Individuals vaccinated during Stage I Preparedness efforts will be instructed to report to hospital employee health departments for evaluation of possible VAEs.

2. **Hospitals (in the event of VAEs reported during after-hours) must be able to provide 24 hour/7 day a week follow-up services for vaccinees and contacts of vaccinees requiring medical attention**.

3. Providers caring for vaccinated employees with potential adverse effects may consult with the NJDHSS at the contact numbers listed below in Section VII.

B. Required hospital staff and resources will include the following (roles and responsibilities are listed in Section II.C.):

1. Infection control professional(s),
2. Employee health department staff, and
3. Emergency department staff.

C. Monitoring of VAE among public health response and hospital response team members

1. Hospital employee health departments and/or infection control professionals will be responsible for the following active hospital-based surveillance activities:

a. Submit to NJDHSS daily surveillance reports that will include a summary of number of persons reporting to employee health, related to vaccine administration, **via email using the spreadsheet provided by NJDHSS.** Daily surveillance reports of VAE evaluations that occur during weekends may be submitted the following Monday.

b. Clinically significant and non-clinically significant VAEs must be documented on a Vaccine Adverse Event Reporting System (VAERS) report form. **Forms may be completed online via the NJ Preparedness Vaccination System (PVS) (internet connection required) or via fax. In either case NJDHSS**

must be notified by phone to ensure prompt review of VAERS report.

i. Hospitals are requested to enter reports into NJPVS or to fax reports to NJDHSS within the timeframe specified in Section I. NJDHSS will then review the reports, enter paper forms into NJ PVS, and then transmit data to LINCS epidemiologists and the CDC.

ii. Completed VAERS forms must be filled out as completely as possible. **The Patient Vaccination Number, a unique number assigned to each vaccinee at the time of vaccination, must be noted on the form.**

iii. The CDC expanded VAERS form, "Smallpox Vaccine Adverse Events Reporting and Surveillance Worksheet," which requests additional clinical information, must be completed for each person with VAE.

2. Any vaccinee evaluated in the emergency department (when the hospital employee health department is closed or not available) must be reported to the hospital employee health department and/or infection control professional for surveillance purposes as described above.

D. Monitoring for adverse events among **contacts of vaccinees** (inadvertent inoculation of vaccinia virus through contact transmission)

1. Because vaccinia virus can be transmitted from the vaccination site if not appropriately covered and cared for, adverse events have been known to occur in contacts of vaccinated persons (e.g., eczema vaccinatum).

2. If an adverse event is suspected or identified in a contact of a vaccine recipient, vaccinees or their affected contacts will be instructed to contact NJDHSS. NJDHSS will make arrangements for prompt follow-up at a hospital emergency department convenient for the affected contact.

3. Hospitals should submit a VAERS report, as specified in Section II.C., on the affected contact experiencing the adverse event. Such reports will be coded as the result of secondary transmission.

III. Active regional vaccination clinic-based surveillance

A. Introduction: All individuals vaccinated during Stage I Preparedness efforts will be instructed to report to regional vaccination clinics at day 6-10 after vaccination for evaluation of vaccine take and possible vaccine adverse events (VAEs).

B. **Regional vaccination clinic staff will evaluate vaccinees and examine their vaccination sites for takes and evaluate for possible adverse events related to the vaccine. At this point the initial diary card is collected and a second diary card, maintained until the vaccine site scab falls off, is given to the vaccinee.**

1. Regional vaccination clinic staff will record any observed adverse events on VAERS form. VAERS forms will be collected by NJDHSS for data entry into NJ PVS.

2. Regional vaccination clinic staff will refer persons with adverse events for follow-up evaluation at the hospitals designated for their follow-up. NJDHSS should be notified of individuals experiencing known or suspect adverse events.

3. Any person with an adverse event that might warrant hospitalization or VIG/cidofovir treatment will be referred for immediate medical treatment at the hospital designated for his/her follow-up. The evaluating physician should contact NJDHSS immediately in order to begin the process for VIG/cidofovir release from CDC.

C. Regional vaccination clinic staff may consult with the NJDHSS at the contact numbers listed below in Section VII.

IV. Data management, information sharing, updates and follow-up procedures

A. NJDHSS data management and information sharing

1. NJHDSS staff will enter paper VAERS reports to NJ PVS. All reports, including those submitted online into PVS at the hospitals, will be reviewed daily by NJDHSS staff.

2. NJDHSS staff will maintain a system to track active hospital-based daily surveillance reports (i.e., track which hospitals are reporting) and will generate summary reports on hospital reporting.

   a. Data collected will include demographic and vaccination information to calculate adverse event rates.
   b. NJDHSS staff will receive national VAERS summary reports daily from the CDC and will disseminate this information to hospitals.

3. NJDHSS staff will transmit daily VAERS reports and other VAEs information to LINCS epidemiologists and to CDC.

B. NJDHSS will conduct regular conference calls with LINCS epidemiologists to provide updates on surveillance and other issues related to VAEs. LINCS epidemiologists will communicate these updates to hospitals in their LINCS region.

C. LINCS epidemiologists will coordinate and conduct follow-up on persons within their LINCS region who experienced VAEs. Follow-up will include obtaining information on these persons' clinical disposition and outcome.

V. Evaluation, treatment and referral of persons with VAEs

A. Initial evaluation of vaccinees

1. Hospital employee health departments will perform initial evaluations of persons with suspected VAEs, referring persons to appropriate subspecialists (e.g., infectious diseases, dermatology, neurology, ophthalmology, allergy/immunology).

2. Consultation for clinicians—in the event that hospital physicians require consultation, physicians should contact NJDHSS for assistance. NJDHSS will provide 24/7 coverage for answering questions and routing requests for vaccine immune globulin (VIG) or cidofovir to CDC. NJDHSS will contact the following, if further assistance is required:

   a. Clinical Immunization Safety (CISA) Network, which consists of four geographically diverse centers recently funded by CDC to evaluate individual clinical adverse events reported to VAERS.
   b. CDC.

3. VIG/cidofovir use-- in the event VIG/cidofovir use is indicated (after consultation with NJDHSS):

   a. NJDHSS will make requests for VIG/cidofovir through the CDC Drug Services Center.

   b. For each person receiving VIG or cidofovir, appropriate paperwork should be returned to the CDC directly by the provider. This paperwork will accompany the VIG/cidofovir.

VI. Contact information

A. **NJDHSS is available for consultation on the surveillance, evaluation, management and treatment of VAEs 24/7.**

1. During M-F, 8am-4pm: Infectious and Zoonotic Disease Program, 609-588-7500 or 609-588-3121.

2. During weekends, holidays and off-hours: Communicable Disease Service On-Call, 609-392-2020.

B. CDC has several hotlines available for consultation.

1. Public Response Service—to provide general information on smallpox vaccine and VAEs

   M-F, 8am-11pm; Sat-Sun., 10am-8pm EST
   English, 888-246-2675
   Espanol, 888-246-2857
   TTY, 886-874-2646

2. Clinician Information Line—to provide information to clinicians regarding smallpox vaccine, in particular, for VAEs

   24/7, start date Monday 1/27/2003
   877-554-4625

VII. Additional resources

NJDHSS website: www.state.nj.us/health

CDC smallpox website: www.cdc.gov/smallpox

National Immunization Program website: www.cdc.gov/nip

Clinical Evaluation Tools: www.bt.cdc.gov/agent/smallpox/vaccination/clineval